

Applicants: Ziv Sandalon et al.  
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#### **REMARKS**

Claims 1-2, 4-13, 16-20, 22-37, 41-43 and 45-47 are pending in the subject application.

In view of the arguments set forth below, applicants maintain that the Examiner's rejection has been overcome and respectfully request that the Examiner reconsider and withdraw same.

#### **Formalities**

Applicants acknowledge the Examiner's allowance of claims 29-34 and withdrawal of all outstanding claim rejections not repeated in this Office Action. Applicants also acknowledge the Examiner's approval of the corrected formal drawings submitted by applicants on October 9, 2003.

#### **Claim Rejections Under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claims 1-2, 4-13, 16-20, 22-28, 35-37, 41-43 and 45-46 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner stated that applicants have amended claims 1, 18 and 35 to recite that the nucleic acid constituent of the

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infectious SV40 particle "...is not a nucleoprotein...". The Examiner alleges that there is no support in the specification for this broad negative limitation with regard to the nature of the nucleic acid component of the recited infectious SV40 particle complexes. The Examiner states that applicants point to support for this limitation on page 34 of the specification; however, this portion of the specification only refers to the possible role of LCR elements involved in *in vivo* formation of "...higher order nucleoprotein structures...". The Examiner stated that this is a new matter rejection.

In response, applicants respectfully traverse. Applicants note that the pending claims are directed to the *in vitro* packaging of SV40. Applicants also point out that the description on page 34 of the subject application, specifically lines 3-21, describes *in vitro* packaging of nucleic acids in SV40. In this paragraph of the subject specification applicants compare the *in vitro* and *in vivo* nucleic acid packaging mechanisms of SV40 (see page 34, lines 3-4).

More specifically, applicants teach the following on page 34, lines 3-21:

- (i) *in vitro* packaging utilizes naked DNA, prepared in *E.Coli* (see lines 6-7);
- (ii) potent regulatory sequences, such as  $\beta$ -globin LCR, which interfere with viral packaging *in vivo* (cite

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omitted), do not interfere with *in vitro* packaging because these LCR elements (i.e. regulatory sequences such as  $\beta$ -globin LCR) form higher order nucleoprotein structures *in vivo* only (see lines 7-14); and

(iii) the use of supercoiled plasmid DNA *in vitro* is predicted to relieve the packaging problems encountered *in vivo* which are created by the formation of nucleoproteins by the LCR elements (see lines 14-15).

Therefore, applicants teach that *in vitro* packaging of nucleic acids in SV40 does not involve nucleoprotein formation.[emphasis added]

Accordingly, applicants maintain that the limitation, "wherein the nucleic acid is not a nucleoprotein", in claims 1, 18 and 35 is adequately supported by the subject specification and is not new matter because applicants teach that *in vitro* packaging of nucleic acids in SV40 does not involve nucleoprotein formation.[emphasis added]

In view of the above remarks, applicants maintain that claims 1-2, 4-13, 16-20, 22-28, 35-37, 41-43 and 45-46 satisfy the requirements of 35 U.S.C. §112, first paragraph and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

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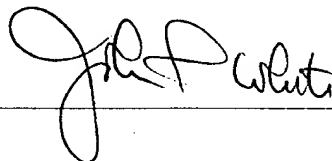
Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

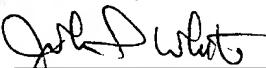
No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



3/12/04

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Date